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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,103	02/17/2004	Hector F. DeLuca	1256-00947	9902

26753 7590 04/22/2005

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EXAMINER	
QAZI, SABIHA NAIM	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 04/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/780,103	DELUCA ET AL.	
	Examiner	Art Unit	
	Sabiha Qazi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *49,54-59,64-69,74-79 and 84-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *49, 54-59, 64-69, 74-79 and 84-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

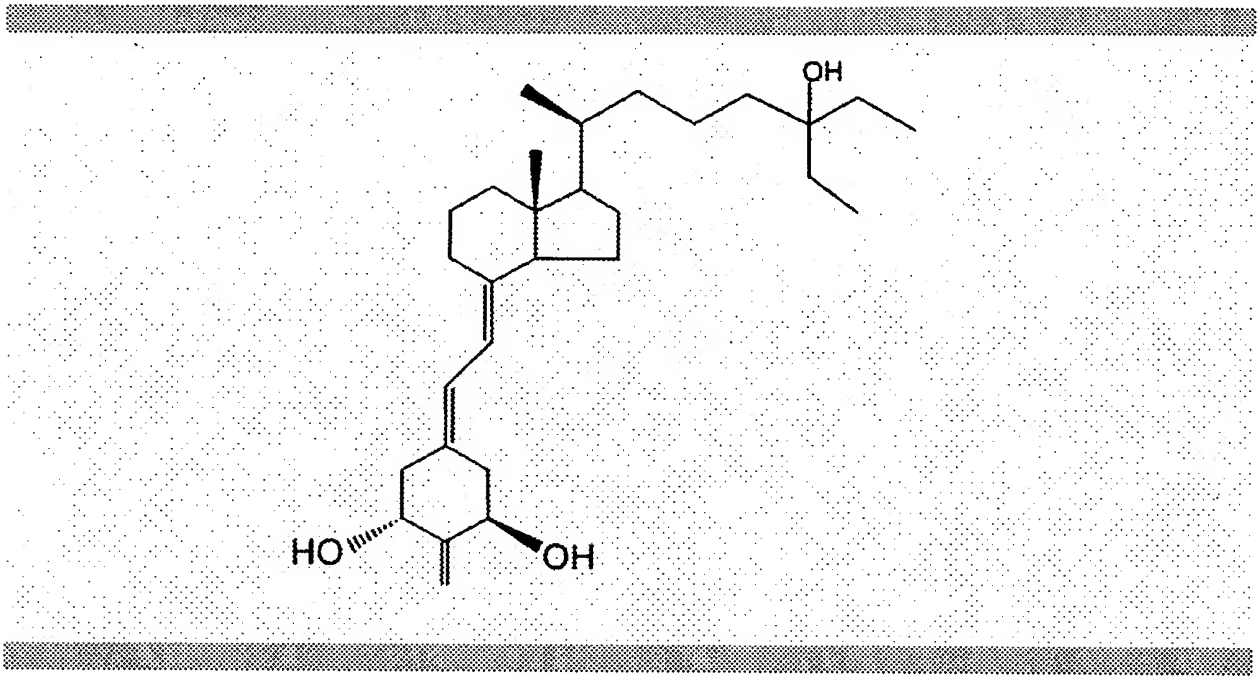
Final Office Action

Claims 49, 54-59, 64-69, 74-79 and 84-88 are pending. No claim is allowed. Acknowledgement is made of the response filed on January 5, 2005. Amendments are entered.

Response to Arguments

Applicant's arguments were fully considered but were not found persuasive. Biological activity of 2-methyl 19-nor 20-S compounds is disclosed. It is not clear how instant compounds are enabled for the said diseases. Examiner requests the Applicant is requested to explain in detail how the method of use of the compounds is disclosed. Even though claims are limited to certain cancers the rejection under 35 U.S.C. 112, first paragraph, is maintained because the disclosure does not commensurate with the scope of claims. Furthermore it is not clear how 26, 27 dihomo is better than dimethyl analogs. Claims 49 and 54-58 are amended however, the basis of double patenting rejection is the same therefore, this rejection is maintained. When a clear understanding of the unexpected activity of dihomo compound vs dimethyl compound would be established this rejection will be withdrawn.

The claims are drawn to a method of treating a **cancerous disease selected from a group consisting of leukemia, colon cancer, breast cancer, and prostate cancer comprising** administering to a patient with said disease an effective amount of 20(S)-1alpha, 25-dihydroxy-z-methylene-26,27-dihomo-19-nor vitamin D3 and its analogues one of them having the following structure (claim 49).



Double Patenting

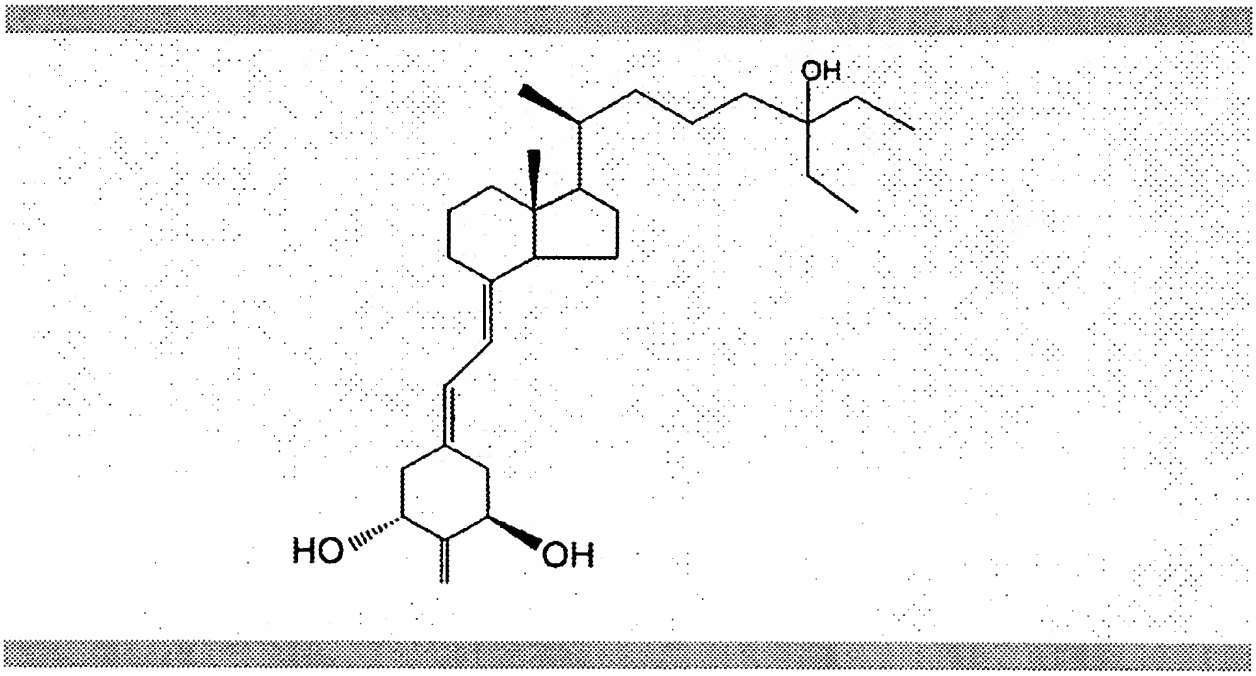
The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

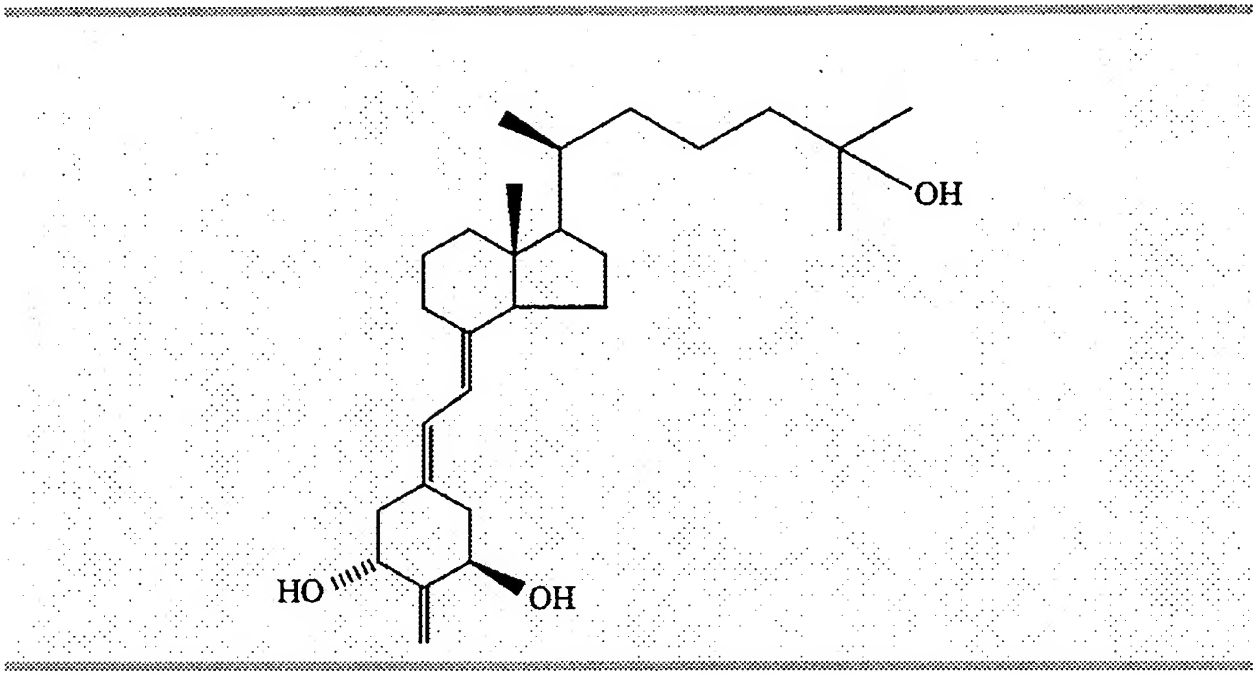
provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 49, 54-58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-22 of copending Application No. 10/669,990. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications' claims are drawn to a method of treating a cancerous disease comprising administering to a patient with said disease an effective amount of a composition.



20(S)-1alpha,25-dihydroxy-z-methylene-26,27-dihomo-19-nor vitamin D3 (Application '103)



2-methylene-19-nor-20(S)-1aplha,25-dihydroxy vitamin D3 (Application '990)

Instant claims differ from the copending application in having 1 methyl group more at 26,27 position. The compound of Application '990 is a homologue of the presently claimed invention. Homologues are known to have similar properties. Therefore, the presently claimed method(s) would have been obvious to one skilled in the art at the time of invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

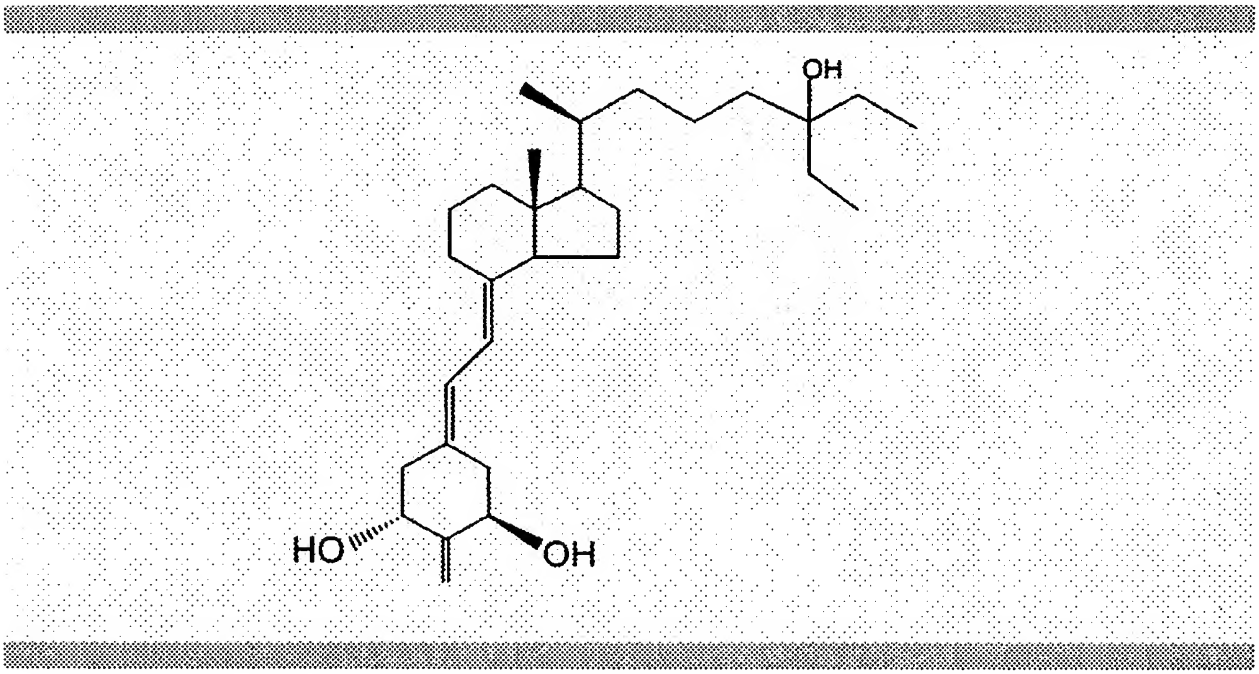
Claims 49, 54-59, 64-69, 74-79 and 84-88 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of use of certain compounds does not reasonably provide enablement for the method of use of all the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention: The claims are drawn to a method of treating a cancerous disease comprising administering to a patient with said disease an effective amount of 20(S)-

1alpha,25-dihydroxy-z-methylene-26,27-dihomo-19-nor vitamin D3 (and its analogues) having the structure:



The predictability or unpredictability of the art: There is lack of predictability in the in the pharmaceutical art.

The breadth of the claims: The claims are broad; they include methods for treating "cancerous diseases," including leukemia, colon cancer, breast cancer, prostate cancer, etc.

The amount of direction or guidance presented: On pages 27 and 28 of the Specification, the VDR binding properties and HL-60 differentiating activities are shown, as

disclosed in Table 3. On page 23 of the Specification, lines 21-26, the Applicants disclose, "20(S)-1alpha,25-dihydroxy-2-methylene-26,27-dihomo-19-nor vitamin D3 is extremely potent in inducing differentiation of HL-60 cells to the monocyte. These results illustrate the potential of the 20(S)-1alpha,25-dihydroxy-z-methylene-26,27-dihomo-19-nor vitamin D3 compounds as anticancer agents, especially against leukemia, colon cancer, breast cancer, and prostate cancer, or as agents in the treatment of psoriasis."

There is no guidance in the disclosure on how to use the invention successfully for the treatments of so many cancerous diseases.

In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result."

The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971).

A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See In re Riat et al. (CCPA 1964) 327 F2d 685, 140 USPQ 471; In re Barr et al. (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

The quantity of experimentation necessary: Since there is not enough guidance presented in the disclosure, one skilled in the art at the time of invention would have to go through undue experimentation to make and use the presently claimed invention.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SABIHA QAZI, PH.D
PRIMARY EXAMINER

Sunday, April 17, 2005